

REMARKS

The Office Action of December 13, 2004 has been reviewed, and the Examiner's comments carefully considered. The present Amendment amends claims 1-14 in accordance with the originally-filed specification. Claims 1-18 are pending in this application, and claims 1 and 6-9 are in independent form.

The undersigned appreciates the Examiner's indication of allowable subject matter of claims 6-9 and 15-18. Claims 6-9 have been rewritten in independent form and should be allowed. Claims 15-18 depend respectfully from claims 6-9 and should also be allowed.

Informalities

The specification has been amended to update the status of parent application 10/141,723. Applicant respectfully asserts its wishes to maintain the brackets in claim 2 so that the present application is consistent with its parent application. Further, an end bracket has been placed in claim 3 to complete the bracket match. Removal of the formality objections is respectfully requested.

Rejections based on U.S. Patent No. 6,790,830 and WO Patent Application 2002/92032

The Examiner has rejected claims 1-5 and 10-14 under the judicially created doctrine of obviousness-type double patenting. In particular, these claims have been rejected over claims 1-10 of U.S. Patent No. 6,790,830 (hereinafter, the '830 patent). Enclosed herewith and incorporated herein by reference is a Terminal Disclaimer. The filed Terminal Disclaimer overcomes the double patenting rejection over the '830 patent. Withdrawal of this double patenting rejection is respectfully requested.

The Examiner asserts that the effective filing date of claims 1, 2, 6-11 and 15-18 is deemed to be October 29, 2003, the filing date of the present application. However, the aforesaid claims should be granted an effective filing date of November 4, 2002, the filing date of the priority Korean Patent Application No. 10-2002-0067751. A true English translation of the certified copy of the Korean Application is enclosed herewith. A claim for priority under 35 U.S.C. § 119 was filed for the present application on March 19, 2004. Thus, WO Patent Application 2002/92032, which was published on November 21, 2002 should be removed as a prior art reference to the present application and is not available as prior art against claims 1, 2, 6-11 and 15-18 under 35 U.S.C. § 102(a).

Further, the Examiner asserts that the '830 patent is available as prior art against claims 1, 2, 6-11 and 15-18 under 35 U.S.C. § 102(e). However, pursuant to 35 U.S.C. § 103(c)(1), the '830 patent does not qualify as prior art and shall not preclude the patentability of the claimed invention because at the time the claimed invention was made the subject matter was owned by and subject to the obligation of assignment to the same entity, namely, LG Household & Health Care Ltd. Thus, the '830 patent should be removed as prior art for the purposes of 35 U.S.C. § 102(e).

Additionally, the Examiner asserts that the '830 patent is available as prior art against claims 1-5 and 10-14 under 35 U.S.C. § 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(e) and the conflicting inventions were not commonly owned at the time the present application was made. However, as averred above, the '830 patent and the present application were commonly owned and assigned at the time the invention in the present application was made. Thus, the '830 patent should be removed as prior art for the purposes of 35 U.S.C. § 103(a).

The Examiner has rejected claims 1, 2, 10 and 11 under 35 U.S.C. § 103(a) for asserted obviousness over the '830 patent. As discussed above, the '830 patent should be removed as a prior art reference. Thus, the rejection of claims 1, 2, 10 and 11 over the '830 patent is moot.

The Examiner has rejected claims 1, 2, 10 and 11 under 35 U.S.C. § 103(a) for asserted obviousness over the WO Patent Application 2002/92032. As discussed above, the WO Patent Application 2002/92032, which was published on November 21, 2002, should be removed as a prior art reference. Thus, the rejection of claims 1, 2, 10 and 11 over the WO Patent Application 2002/92032 is moot.

Rejection of claims 1 and 10 under 35 U.S.C. § 102(b) and 103(a)

Claims 2-5 and 11-14 contain allowable subject matter not rejected over Seebach (U.S. Patent No. 4,771,122) and/or Viskov (U.S. Patent Application Publication 2001/0025025). Regarding the remaining claim rejections under 35 U.S.C. §§102(b) and 103(a), the applicant indicates the following differences between the claimed invention and the Seebach and Viskov references.

The present invention, as defined by amended claims 1 and 10, is directed to a method for treating alopecia and promoting hair growth with a 3-position analog of

cyclosporin represented by Formula 1. The characteristic feature of the invention is that the cyclosporin derivatives have **unexpected hair-growth effects** compared with those of other cyclosporins.

Seebach discloses cyclosporins having an optically active α -N-methylated α -amino acid residue of the (D)-configuration at the 3-position, processes for the production thereof, and their uses as pharmaceuticals, in particular for their immunosuppressive, anti-inflammatory and anti-parasitic activity. Even though the cyclosporins of Seebach are described to have lower undesirable side-effects, there is no mention of their hair-growth effects. Accordingly, Seebach neither anticipates nor renders obvious the use of cyclosporin in a method of treating hair growth according to the present invention.

In Viskov, a method for preparing an intermediate polyanion for preparing cyclosporin derivatives is disclosed. Even though Viskov teaches cyclosporin analogs of claim 1 of the present invention, it neither describes nor suggests their unexpected hair-growth effect. Accordingly, Viskov neither anticipates nor renders obvious the present invention.

Moreover, prior to the present invention, one of ordinary skill in the art would not expect the cyclosporins of Formula 1 to have maintained their hair growth effects since **not all cyclosporin derivatives after being modified have maintained their efficacy, in terms of hair growth**, as evidenced by the following publications (copies of which are submitted in an Information Disclosure Statement):

1. Sandoz Pharma AG investigates various analogues including (D-MeVal)¹¹-CsA, MeBmt(3-keto)¹-Val²-CsA and (MeIle)⁴-CsA and concludes that none of the analogues were able to induce hair growth (*Advances in Pharmacology*, Vol. 35, pp. 115-246, 1996).

2. Cyclosporin H, a derivative with a modification at 11th residue of cyclosporin A, does not have the promoting effect of hair growth, as indicated in R. Paus, *et al.*, "Hair Growth Control by Immunosuppression," *Arch. Dermatol. Res.* (1996) 288: 408-410 (see in particular Table 1).

3. In Kim *et al* (U.S. Patent No. 6,521,595), there are several chemically modified analogues with no hair growth effect left (see column 11, lines 47-64).

4. In PCT publication WO 01/35913, it is described that other cyclosporin derivatives, where the MePhe, Pipecolic acid, Sarcosine or MeNov is substituted at 4th residue of the cyclosporin A, have no hair-growth effect (see page 24).

Considering the above, the cited references do not teach the use of the cyclosporin derivatives of Seebach and Viskov for promoting hair growth. Likewise, one of ordinary skill in the art would not be led to use the cyclosporins of Formula 1 of the present invention for treating alopecia and promoting hair growth.

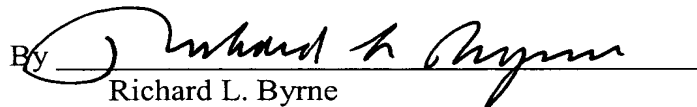
Accordingly, the references cited by the Examiner, either alone or in combination, fail to teach or suggest the present invention.

CONCLUSION

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of pending claims 1-18 are respectfully requested.

Respectfully submitted,

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